K052469

510(k) SUMMARY

(As required by 21.CFR.807.92)

Introduction: According to the requirements of 21 CFR.807.92, the following information provides sufficient data to understand the basis for a determination of substantial equivalence.

Submitted By:

Healthpia America Corp.
211 Warren Street, #209
Newark, NJ 07103

JUN - 5 2006

Contact Person:

Steven Kim
Phone: 973-286-7676
Fax: 212-202-5173

Date Summary, Prepared: February 16th, 2006

Device Name:
Propriety Name: GlucoPack™
Common Name: Blood Glucose Test System
Classification Name: Class II, 862.1345 Glucose Blood Tester

Predicate Device: We claim substantial equivalence to the LifeScan, Inc., OneTouch® Ultra®, EasyGluco™

Device Description: The GlucoPack™ Meter device is used along with the GlucoPack™ Test Strip to measure the glucose level in whole blood.

Intended Use: The GlucoPack™ Diabetes Monitoring System is used for the quantitative measurement of glucose level in whole blood as an aid in monitoring the effectiveness of diabetes management in the home and in clinical settings. GlucoPack™ System is for testing outside the body (in vitro diagnostic use only). Testing sites include the traditional fingertips only.

Comparison to Predicate Device: The Healthpia Corp. GlucoPack™ Module is substantially equivalent to the other products in commercial distribution intended for similar use. The most notable, it is substantially equivalent to the currently marketed item, the OneTouch® Ultra® by LifeScan, Inc.

Conclusion:	The FREEDOM™ Blood Glucose Monitoring System is substantially equivalent to the following predicate devices: K024194 – LifeScan, Inc. OneTouch® Ultra® K984261 – LifeScan, Inc. SURESTEP® K021513 – Roche Diagnostics Corp. Accu-Chek Advantage

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 5 2006

Mr. Steven Kim
President
HealthPia America Corp.
211 Warren Street, # 209
Newark, NJ 07103

Re: k052469
Trade/Device Name: GlucoPack
Regulation Number: 21 CFR§ 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: May 24, 2006
Received: May 24, 2006

Dear Mr. Steven Kim;

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:K052469

Device Name: GlucoPack™

Indications For Use: The GlucoPack Diabetes Monitoring System is intended for use in the quantitative measurement of glucose in whole blood taken from the fingertip. Testing is done outside the body (in Vitro diagnostic use). It is indicated for use at home (over the counter (OTC)) by persons with diabetes mellitus, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. It is not intended for use on neonates.

Prescription Use _X___ (Part 21 CFR 801 Subpart D) (AND/OR) Over-The-Counter Use__X___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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